REMARKS

In the Office Action mailed from the United States Patent and Trademark Office on January 19, 2010, claims 1, 5, 7, and 10-12 were rejected under 35 U.S.C. 112, as failing to comply with the written description requirement, Claims 1, 2, 7-10 and 12 were rejected under 35 U.S.C. 103(a) as being unpatentable over USPN 5,250,035 to Smith et al in view of USPGPub2002/0123723 to Sorenson et al, and Claims 3-6 and 11 were rejected under 35 U.S.C. 103(a) as being unpatentable over Smith et al and Sorenson et al in further view of USPGPub 2002/055715 to Young et al. Claims 1-12 are in the current application, claims 1-12 were rejected.

Claim Objections

Claims 1-12 are objected to because of the following informalities: the claims inconsistently refer to "facial" compartments as well as "fascial" compartments. Applicant has amended the claims, as well as the specification, to ensure all instances of the term "fasical" are spelled properly. Accordingly, Applicant respectfully requests that the objection be withdrawn at this time.

Rejections under 35 U.S.C. Section 112

Claims 1, 5, 7, and 10-12 are rejected under 35 U.S.C. 112, first paragraph as failing to comply with the written description requirement. Applicant has amended the claims to read "between one and two millimeters" as suggested in the pending Action, and requests that the Section 112 rejection be withdrawn at this time.

Rejections under 35 U.S.C. 103

Claims 1, 2 and 7-9 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No 5,250,035 ("Smith") in view of U.S. Patent Publication No. 2002/0123723 ("Sorenson"). Applicant respectfully submits that the cited references, alone or in combination, do not teach or suggest all the limitations recited in the claim set provided herein. In particular

independent claims 1, 5 and 7 contain limitations drawn to a hollow needle having a plurality of fenestrations wherein the fenestrations are spaced at intervals within two millimeters of each other, wherein the needle is structured to allow location of all of the fenestrations to be located within the fascial plane during injection,. The plurality of fenestrations as claimed provides the unexpected benefit of allowing a method for properly locating and anesthetizing a fascial compartment containing a nerve while avoiding intravascular injection and/or inadvertent penetration of the affected nerve. Smith's disclosure related to a spinal catheter and Sorensen's disclosure related to a method for diffusing medication in a subcutaneous injection fail to read on the peripheral nerve block needle of the present application.

One of skill in the art would not find it obvious to overcome the differences to arrive at the claimed invention. The differences between various types of needles call for differing structures and the differing structures greatly affect their suitability for differing uses. For example, using the spinal catheter system of Smith for providing a nerve block procedure would be extraordinarily difficult due to the difficulties in placing the needle outlet of Smith within the fascial compartment. Reference may be made to Smith's description of use of the cannula beginning at column 4 line 53. The procedure starts with an introducer making an initial passage or puncture that terminates adjacent the dura. (Col. 4 lines 60-64; Col. 3 lines 23-26) The system of Smith is then advanced slightly to part the dura to access the subarachnoid space. (Col. 4 lines 62-69; Col.5 lines 6-10) One of skill in the art would thus understand that the system of Smith is not properly intended for blind placement of the cannula deep within tissue, but is instead to be used for the final advancement stage just through the dura itself. This final placement procedure is very different from the nerve block usage of the presently-claimed invention, and those differences provide significant benefits for nerve block procedures.

Similarly, the tubular medication dispersal system of Sorenson is for a very different situation than the nerve block procedure of the presently-claimed invention, and these differences are notable in the differences between the system described by Sorenson and the claimed invention. The system of Sorenson utilizes perforations or striations structured and

arranged to achieve substantially-uniform volume and rate of dispersion of therapeutic fluids cylindrically along the perforated length of the tube. (Col. 3 lines 64-67; Col. 6 lines 35-37) The system of Sorenson is designed for delivery of medication subcutaneously or interstitially. (Abstract, Col. 1 lines 17-20) Thus, the system disclosed in Sorenson is designed for broad and even dispersal of the medication through the system, and one of skill in the art would understand its design as achieving this goal. It should be noted that Sorenson describes the desirable size of striations to achieve this goal, indicating that the striations (shown in Figure 3 at reference number 90, shown for reference on the next page below) should be approximately 5 millimeters in length in one preferred embodiment and approximately 1 centimeter in length in the second preferred embodiment. Figure 3 may be referenced to show that the striations are spaced at approximately their own length. As this is Sorenson's only teaching with respect to the size and spacing of the striations/perforations, Applicant respectfully notes that Sorenson fails to teach the claimed fenestrations spaced at intervals between one and two millimeters of each other as is required by the claims.

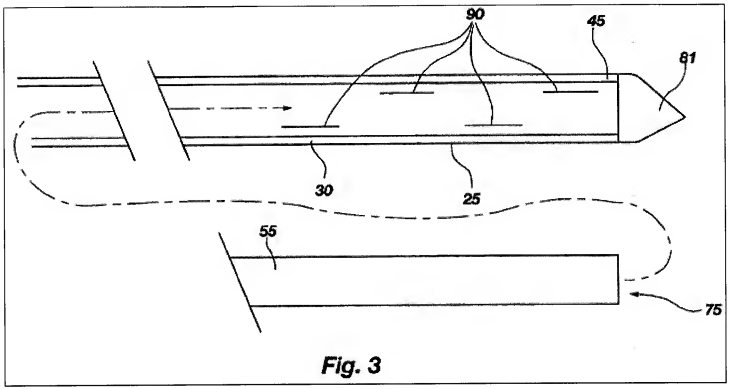

Fig. 3

Because of the different anticipated uses between the claimed invention and the devices disclosed in the cited references, one of skill in the art would not find it obvious to modify those references to change the approximately 5 millimeter spacing of Sorenson to the claimed fenestrations having spacing at intervals within two millimeters of each other. While the Sorenson device is designed to apply medicine uniformly around all the Sorenson openings, the claimed nerve block needle apparatus is designed to position all of the fenestrations within a fascial compartment (which can be very narrow). In this use, the flow through the intramuscular fenestrations is relatively low while the flow within the fascial compartment is higher. (See specification as filed, page 8 line 18 through page 9 line 11.) If a needle having the spacing disclosed in Sorenson (for general pain medicine administration, not for peripheral nerve blocks) were used to attempt a nerve block as disclosed in the present application, the attempt would

likely fail due to the high likelihood that access to the fascial compartment would not be achieved.

Although the differences between Sorenson and the claimed invention are subtle, Applicant respectfully submits that the differences are extremely important and that one of skill in the medical arts would not find it obvious to modify Sorenson to arrive at the claimed invention. Therefore, for at least these reasons, the claims are not made obvious by the combinations of references including Smith and Sorenson.

Additionally, with respect to method claim 7, Applicant respectfully notes that none of the cited references disclose the method steps required by the claim. Specifically, claim 7 requires: "inserting a fenestrated needle into said dermal area, said fenestrated needle comprising a plurality of fenestrations, structured to allow location of all of the fenestrations within the fascial compartment during injection, wherein said plurality of fenestrations are proximate a distal end of said fenestrated needle and are spaced at intervals within two millimeters of each other," "advancing said fenestrated needle slowly through said dermal area and said fascial membrane, whereby at least one of said fenestrations is located within said fascial compartment," and "injecting local anesthetic through said fenestrated needle to induce an efflux of local anesthetic into said fascial compartment while minimizing flow of anesthetic outside the boundaries of the fascial compartment and a corresponding anesthetic block at said affected peripheral nerve." Such features are not taught by any of the cited references, which fail to disclose or discuss any features with respect to fascial compartments. Therefore, for this additional reason, method claim 7 is not made obvious by the cited references, and its dependent claims are similarly allowable.

Because the combination of art does not teach every limitation of the claimed invention, and because one of skill in the art would not find it obvious to modify the art to overcome the differences between the art and the claimed invention, Applicant respectfully requests that the obviousness rejections be withdrawn.

CONCLUSION

If any impediments to the allowance of this application for patent remain after the above amendments and remarks are entered, the Examiner is invited to initiate a telephone conference with the undersigned attorney of record.

DATED this 19th day of May, 2010.

Respectfully submitted,

Michael F. Krieger
Attorney for Applicant
Registration No. 35,232

KIRTON & McCONKIE
1800 Eagle Gate Tower
60 East South Temple
Salt Lake City, UT 84111
(801) 328-3600

JRM/law
4818-4758-2725